

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Plaintiff,

v.

Case No. 2:21-cv-10312

BLUEWILLOW BIOLOGICS, INC.;
ROBIN ROE 1 through 10, gender
neutral fictitious names, and; ABC
CORPORATION 1 through 10 (fictitious
names).

Hon. F. Kay Behm

Defendants.

**DEFENDANT/COUNTER-PLAINTIFF BLUEWILLOW
BIOLOGICS, INC.'S MOTION TO EXCLUDE THE
EXPERT REPORTS AND TESTIMONY OF
ALEXEI ERMAKOV AND SHANE BURNS**

Pursuant to Federal Rule of Evidence 702, controlling law, *Daubert*, and the Court's inherent authority, Defendant/Counter-Plaintiff BlueWillow Biologics, Inc. ("**BlueWillow**"), by and through its under signed counsel, Foley & Lardner LLP, respectfully moves to exclude the Expert Reports and testimony of Alexei Ermakov, Ph.D. ("**Ermakov**") and Shane Burns ("**Burns**") regarding their tests and comparisons of the magnitude of electrostatic charge of Trutek Corp.'s ("**Trutek**") NasalGuard products and BlueWillow's accused NanoBio[®] Protect product.

On January 17, 2023, BlueWillow's counsel met and conferred with counsel for Trutek, explained the nature and bases of this Motion, and requested concurrence in the relief sought. Trutek did not concur.

As explained in more detail in the accompanying Brief in Support, the Court must exclude the expert reports and testimony of Ermakov and Burns as they: (1) created and applied methodologies solely for the purpose of this litigation that have never been used before and that lack independent verification and support in scientific literature; (2) did not use proper controls, deploy basic calibrations, or apply appropriate scientific rigor when conducting tests; (3) failed to verify the contents and integrity of the test samples; and (4) failed to direct their testing, opinions and testimony to relevant and probative information.

Dated: March 15, 2023

Respectfully submitted,

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**BRIEF IN SUPPORT OF MOTION TO EXCLUDE THE
EXPERT REPORTS AND TESTIMONY OF
ALEXEI ERMAKOV AND SHANE BURNS**

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STATEMENT OF ISSUE PRESENTED

1. Whether the Court should exclude the expert reports and testimony of Alexei Ermakov and Shane Burns as they created and applied methodologies for this litigation that have never been used before and that lack independent verification and support in scientific literature.

BlueWillow's answer: **Yes.**

Trutek's answer: **No.**

2. Whether the Court should exclude the expert reports and testimony of Alexei Ermakov and Shane Burns as they did not use proper controls, deploy basic calibrations, or apply appropriate scientific rigor when conducting the testing.

BlueWillow's answer: **Yes.**

Trutek's answer: **No.**

3. Whether the Court should exclude the expert reports and testimony of Alexei Ermakov and Shane Burns as they failed to verify the contents and integrity of the test samples.

BlueWillow's answer: **Yes.**

Trutek's answer: **No.**

4. Whether the Court should exclude the expert reports and testimony of Alexei Ermakov and Shane Burns as they failed to direct their testimony to relevant and probative information.

BlueWillow's answer: **Yes**.

Trutek's answer: **No**.

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I. INTRODUCTION

Alexei Ermakov, Ph.D.’s (“**Ermakov**”) and Shane Burns’ (“**Burns**”) Expert Reports, the testing and results described therein, and proposed testimony should be excluded under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). Ermakov and Burns were asked to run experiments to determine whether Trutek’s products and BlueWillow’s accused product exhibit a similar electrostatic surface charge within an order of magnitude (i.e. 10-fold). Upon suggestion by Trutek, Ermakov used printer paper and Burns used dried pigskin as a substrate for the testing—the surface area on which the test samples were applied. There are several notable methodological flaws with both experts’ tests—each independently serve as a basis for exclusion.

First, Ermakov and Burns failed to use *reliable, tested, and peer reviewed* methodologies. Ermakov made a new apparatus for his experiment, which he had never used before. Both Ermakov and Burns employed methods that were designed solely for purposes of this litigation, which had never been used before and were designed without reference to scientific literature, consultation with other experts in the field, or other independent peer review. Indeed, both admitted that there is *no* literature establishing the validity of the methods they implemented.

Second, Ermakov and Burns did not (a) *use proper controls or testing substrates* (b), *deploy basic calibrations*, or (c) *apply appropriate scientific rigor*.

They did not use substrates that operate similar to live human skin under *in vivo* conditions as required by the claims of United States Patent No. 8,163,802 (“**802 Patent**”) (i.e., application to human nasal passages). Rather, Ermakov and Burns used ordinary printer paper and dry pigskin, respectively—neither of which is predictive of how products operate when applied to moist human nasal passages. The tests were conducted at room temperature, though body temperature is significantly higher. Indeed, Burns admitted he merely relied on Trutek’s assertion that dry pigskin is a suitable substrate and did not do any independent verification.

Ermakov and Burns failed to employ appropriate calibration standards or other procedures for *validation*. Ermakov’s and Burns’ tests show significant discrepancies—strong evidence of unreliability—and are, in fact, *inconsistent* with one another (Ermakov and Burns disagree as to which product has a greater charge). Further, when Burns tested NasalGuard on two separate occasions, he obtained incompatible and varying results, outside of an order of magnitude. This is particularly ironic given the experiments purport to reliably establish that various products exhibit a charge within one order of magnitude of each other.

Third, Ermakov and Burns failed to *verify the contents and integrity of their test samples*. Both ran tests on unidentified material in generic bottles (provided by Trutek) without verifying their contents, how they were prepared, the manufacturer or expiration dates of the alleged samples, or determining whether

safeguards were put in place to prevent contamination. Burns additionally ran his tests on dried pigskin without verifying their integrity. Ermakov applied samples to the printer paper using an “eyeball” approach, speculating that the samples were roughly equal in volume (but later conceding discrepancies in results could be explained by volume variances). Burns similarly did not ensure the test samples contained equal amounts. Rather, Trutek supplied Burns with unidentified samples containing unidentified volumes. Put simply, there is no way to know or verify that the samples tested are what Trutek purported them to be.

Fourth, the Ermakov and Burns test methods and results are not directed at the *appropriate inquiry* or *probative* subject matter. The tests attempt to measure the conductivity of formulations generally, not surface electrostatic charge. Further, while the tests were designed to compare the magnitude of electrostatic surface charge between Trutek and BlueWillow products, surface charge magnitude is not an element of the asserted ’802 Patent claims. In other words, the testing does not relate to any element of the claims, i.e., whether the charge is sufficient to electrostatically attract and inhibit harmful particulate matter. Thus, the test results, even if scientifically valid and verifiable, do not demonstrate that the accused product, NanoBio® Protect (“**NanoBio**”), meets the limitations of the asserted claims. Moreover, Ermakov’s testing was not designed to determine whether the measured charge is positive or negative, another element required by

the '802 patent claims. To summarize, the Burns and Ermakov testing is not probative of or relevant to any issue in the case, as the test results do not demonstrate that NanoBio satisfies one or more elements of the asserted claims. At most, Burns and Ermakov present scientifically dubious testing and results that purport to show a similarity between products related to a feature not recited by the asserted claims. However, black letter law states that one cannot prove infringement by a comparison between an accused product and a patentee's products—as patent claims (not products) define the scope of an alleged invention.

II. FACTUAL BACKGROUND

BlueWillow is a clinical-stage biopharmaceutical company focused on developing intranasal vaccines. (ECF No. 9, Countercl., ¶ 6.) BlueWillow developed and sold NanoBio, an over-the-counter nasal antiseptic that uses BlueWillow's proprietary technology to deliver benzalkonium chloride (BZK), a common skin antiseptic that has been used for more than 75 years. (*Id.* ¶ 7.) NanoBio is now discontinued and is no longer sold in the U.S. (ECF No. 28, Mot. for Leave to File Am. Compl., p. 2; ECF No. 28-1, Kremen Decl., ¶ 7.)

On February 10, 2021, Trutek filed suit alleging one count of infringement of United States Patent No. 8,163,802 (“**802 Patent**”) against BlueWillow with respect to a single product, NanoBio. (ECF No. 1, Compl.). The '802 Patent is attached as Exhibit 6 to the Complaint. (ECF No. 1-6.) Trutek alleges that

BlueWillow's NanoBio directly infringes "at least claims 1, 2, and 7 of the ['802] Patent because the [NanoBio] products possess an electrostatic charge when applied to a person's nasal passages, and they use benzalkonium chloride as a biocide." (ECF No. 1, Compl., ¶ 30.) Representative claim 1 states:

1. A method for *electrostatically inhibiting harmful particulate* matter from *infecting* an individual through *nasal inhalation* wherein a *formulation* is *applied to skin or tissue* of nasal passages of the individual in a thin film, said method comprising:

- a) *electrostatically attracting* the particulate matter to the thin film;
- b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the *formulation* to provide adequate impermeability to the thin film; and,
- c) *inactivating the particulate matter* by adding at least one ingredient that would render said particulate matter harmless.

(ECF No. 1-6 (emphasis added).) Representative claim 2 provides:

2. A *formulation* for *electrostatically inhibiting harmful particulate* matter from *infecting* an individual through *nasal inhalation* wherein the *formulation* is *applied to skin or tissue* of nasal passages of the individual in a thin film, said formulation comprising at least one *cationic agent* and at least one *biocidic agent*, and wherein said formulation, once applied:

- a) *electrostatically attracts* the particulate matter to the thin film;
- b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the

formulation to provide adequate impermeability to the thin film; and,

c) *inactivates the particulate matter* and renders said particulate matter harmless.

(*Id.* (emphases added).)

A. Dr. Amiji's Reports (on Behalf of BlueWillow)

BlueWillow submitted three expert reports from Dr. Mansoor M. Amiji, Ph.D. ("**Dr. Amiji**"): (1) an Opening Expert Report, (*see* ECF No. 55-1), on patent invalidity; (2) a Responsive Expert Report, (**Ex. 1**), to Dr. Edward Lemmo's ("**Lemmo**"), Ermakov's, and Burns' Reports; and (3) a Reply Report to Lemmo's and Amirali Y. Haidri's ("**Haidri**") Reports.

Dr. Amiji has a Ph.D. in Pharmaceutical Science/Pharmaceutics from the School of Pharmacy and Pharmaceutical Sciences at Purdue University. (ECF No. 55-1, Dr. Amiji Opening Report, ¶ 9.) Dr. Amiji's dissertation focused on biomaterials and water-soluble polymers. (*Id.*) Dr. Amiji worked as a Senior Research Scientist for Columbia Research Laboratories, where he worked on polymeric delivery systems for various types of therapeutic agents, including those administered topically to skin and mucosal surfaces. (*Id.* ¶ 10.)

Dr. Amiji is a Distinguished Professor, Professor of Pharmaceutical Sciences in the School of Pharmacy, and Processor of Chemical Engineering at Bouve College of Health Sciences at Northeastern University. (*Id.* ¶ 11.) Dr. Amiji has taught and conducted extensive research in pharmaceutical sciences and served as

the Chairman of the Department of Pharmaceutical Science at Bouve. (*Id.*) He was a Visiting Research Scholar at the Massachusetts Institute of Technology. (*Id.*)

Dr. Amiji has ***over 29 years*** of experience in teaching students in the areas of manufacturing and composition of pharmaceutical formulations, delivery systems, and pharmacokinetics. (*Id.*) He is a consultant to several pharmaceutical companies regarding product development and drug delivery. (*Id.*) Dr. Amiji has published extensively and is ranked as a Thompson-Reuters Highly Cited (top 1%) author in Pharmacology and Toxicology, coauthoring over 60 book chapters and 350 peer reviewed scientific articles. (*Id.* ¶ 14.)

B. Ermakov’s Unprecedented and Untested Methodology

Ermakov’s Expert Report, totaling 3 pages, asserts Trutek’s products and NanoBio “demonstrated the presence of a surface electrostatic charge” and the “surface electrostatic charge measured was . . . approximately (in order of magnitude) similar in all three product samples tested.” (**Ex. 2**, p. 3.)

Prior to this case, Ermakov had not performed any similar testing under any circumstances, including as a consultant. (*See* **Ex. 3**, Ermakov Dep. Tr., 15:6–9.) In fact, Ermakov admitted his experiment was “unique” and “different from, like, anything else [he] ha[d] done before.” (*Id.* at 68:5–8.) His research has never focused on: (1) techniques or instrumentation for measuring electrostatic surface charge of pharmaceutical formulations, (2) measuring electrostatic surface charge

of water-in-oil nanoemulsions, (3) techniques or instrumentation for measuring electrostatic surface charge for pharmaceutical products that are intended to be applied to the human skin, or (4) techniques or instrumentation to measure the electrostatic surface charge of pharmaceutical products that function through electrostatic forces. (*Id.* at 68:5–69:3.) To the contrary, his only experience in testing products for electrostatic surface charge is for this litigation. (*Id.* at 71:2–5.)

Ermakov conducted two rounds of testing using a new apparatus (which he never had used before), built for the express purpose of supporting his testimony and Trutek’s infringement claims. (*See id.* at 23:3–15.) He did not consult any of his colleagues, or anyone else, to discuss the validity of his new testing process and apparatus. (*Id.* at 30:2–6, 46:6–16, 74:6–8.) Ermakov’s apparatus and procedures have never been peer reviewed. (*Id.* at 75:21–23.) Ermakov is not aware of any publications related to his novel apparatus or methodology. (*Id.* at 75:11–20.) Further, Ermakov did not review any academic or scientific literature when crafting his never-used-before apparatus and testing procedure. (*Id.* at 79:13–80:1.)

Using his new approach, Ermakov accepted samples of unidentified material provided by Trutek in generic bottles marked with numbers (e.g., 1, 2, and 3) without any knowledge regarding their preparation or contents. (*Id.* at 42:19–43:2, 44:5–8, 79:9–12.) Upon Trutek’s suggestion, Ermakov placed these unidentified materials on ordinary printer paper as a substrate. (*See id.* at 19:5–23.) Notably,

Ermakov does not know if ordinary printer paper is commonly used as a substrate for testing these types of formulations, because he does not “have much knowledge of other instances where someone needed to test the charge of some substance” and does not “have that information.” (*Id.* at 99:8–14.) Ermakov crudely soaked the papers with the unidentified samples, but does not know how much of each sample he used because he “didn’t bother with really accurate measurements of how much sample was applied.” (*See id.* at 85:3–10.) Eyeballing it, he waited until the samples “looked dry.” (*Id.* at 104:6–20.) He then put the paper in an apparatus that he never calibrated because he would have needed a sample of a material with a known charge, which he never bothered to obtain. (*See id.* at 95:22–96:1.)

Ermakov’s apparatus purports to measure the presence and amount of charge, but not polarity (i.e., if the charge is positive or negative). (*Id.* at 98:2–6.) After placing the samples in the apparatus, Ermakov read a screen and handwrote values. (*Id.* at 57:4–7.) He did not replicate the experiment because he assumed the results would be the same. (*Id.* at 107:20–23.) Extrapolating from these results, Ermakov concluded the unidentified samples had an electrostatic charge within “an order of magnitude”—i.e., ten times the charge—of each other (*Id.* at 110:12–22.) He then roughly estimated the electric charges.

For his report, Ermakov assigned the identify of each test sample based on Trutek’s representations. (*Id.* at 87:3–16.) With this unverified information,

Ermakov concluded that Trutek's products had an average charge that was greater than BlueWillow's product. (*Id.* at 116:17–22.) Acknowledging inconsistent results with Burns with respect to the amount of charge measured for each product, Ermakov speculates an error could have occurred because of the application of different volumes for each sample. (*See id.* at 115:4–116:6, 119:19–119:20.)

C. Burns Report

Burns's Expert Report is a scant 6 page summary that asserts: (1) "TTK-NS; NasalGuard Misting Spray (Nasal Spray): Range was between 0.24 and 0.27 and, the average charge was 0.25 nC," (2) "BW-NBP; BlueWillow NanoBio Protect (Solution): Range was between 0.09 and 0.85 and, the average charge was 0.43 nC"; and (3) "[t]he two test products i.e., NasalGuard Misting Spray (Nasal Spray) and BlueWillow NanoBio Protect (Solution) both demonstrated the presence of a surface electrostatic charge of similar order of magnitude." (**Ex. 4**, p. 6.)

For his experiment, Burns was given dry pigskin by Trutek and instructed to use it as a substrate. (**Ex. 5**, Burns Dep. Tr., 30:22–31:2.) Burns does not know where the pigskin was obtained, when it was obtained, or how it was stored. (*Id.* at 130:14–22). He did nothing to test the integrity of the pigskin. (*Id.* at 131:10–17.) While Trutek asserted that dry pigskin is similar to live human skin, Burns has no way to determine if this is true as he would have had "to perform that test," which

he did not. (*Id.* at 43:5–14, 111:5–10.) Burns admitted there is no published paper on similar testing. (*Id.* at 113:25–114:10).

Tellingly, Burns has never used pigskin as a substrate before. (*Id.* at 43:23–44:4, 44:20–24.) Burns has also never tested electrostatic charge using the methodology applied in this case, on any substrate. (*Id.* at 99:3–13, 110:6–10.) Burns also confirmed that there are no industry standards for testing electrostatic charge of products on pigskin. (*Id.* at 94:7–11.) Burns has no experience in testing products like NanoBio, i.e., an oil-in-water nanoemulsion. (*Id.* at 102:7–9.) There is also no industry standard for testing electrostatic charge of liquids, generally. (*Id.* at 93:4–17.) As with Ermakov, Burns was provided generic bottles containing the test samples, for which he did not know their contents or method of preparation. (*See id.* 48:7–11, 53:12–54:8.) Trutek, not Burns, then applied the samples to the pigskin. (*See id.* 51:7–13.)

Burns let the samples dry and used an ETS Model 230 to obtain readings. (*See Ex. 4*, Burns Report, p. 5.) Burns ran his tests on several samples of pigskin coated in unidentified samples, but did not record the results based on each test individually. (*Ex. 5*, Burns Dep. Tr., 148:8–16.) Instead, he calculated an average that failed to account for the charge of the pigskin substrate. (*Id.* at 148:17–23.) Burns then concluded that the unidentified products' electric charges were within the same order of magnitude. (*Id.* at 162:17–21.) Notably, Burns reached the

opposite result of Ermakov when concluding BlueWillow’s product exhibited a higher charge than Trutek’s product. (*Id.* at 163:15–164:10.)

Separately, Burns tested Trutek’s NasalGuard product on another occasion using the same procedure, but obtained inconsistent measurements that were more than an order of magnitude (i.e., more than 10-fold) different. Burns’ July 30, 2019 Report, comparing NasalGuard to Zicam® Cold Remedy, determined that Trutek’s NasalGuard had an average surface electrostatic charge of 16.97 and charge per square centimeter of .146. (**Ex. 6**, Burns July 30, 2019 Report, p. 3.) However, for the test conducted for this litigation, Burns determined NasalGuard had an average surface electrostatic charge of .25 and a charge per square centimeter of .003. (**Ex. 4**, Burns Report, p. 5; *see also* **Ex. 5**, Burns Dep. Tr. 67:11–15.)

D. Dr. Amiji’s Responsive Report

Dr. Amiji’s Responsive Report, based on his experience and knowledge in the relevant field, identifies examples of the “numerous flaws” contained in the Ermakov and Burns Reports and testing methodologies. (**Ex. 1**, ¶ 39.)

First, the tests are not indicative of how NanoBio functions when applied to human nasal passages, *i.e.*, under the *in vivo* conditions required by the ’802 Patent asserted claims. Specifically, paper and dried pigskin have different barrier properties, lack blood vessels, and have a different rate of variability when compared to human skin. (*See id.* ¶¶ 39, 42.) Despite assertions to the contrary,

tests conducted on paper and dry pigskin are not a reasonable predictor of how a pharmaceutical product operates in and on human nasal passages, which are generally very moist. (*Id.* ¶ 42.) As the tests were conducted at room temperature, they are also not indicative of how the products operate at body temperature (which is significantly higher). (*Id.* ¶ 42.)

Second, neither test includes calibration standards or other procedures for validation. (*Id.*) Notably, the tests have significant discrepancies, highly suggesting unreliability, and are ***inconsistent*** with one another. (*See id.* ¶¶ 39, 44–46.)

Third, the Ermakov and Burns tests purportedly measure the conductivity of formulations, not surface electrostatic charge. (*Id.* ¶ 40.) Likewise, the Reports lack any indication that the controls, methods, and results of the experiments demonstrate NanoBio meets any limitation of the asserted claims. (*Id.* ¶¶ 39–40.)

III. LEGAL STANDARD

As the proponent of expert testimony, Trutek bears the burden of establishing its admissibility. *EEOC v. Kaplan Higher Educ. Corp.*, 748 F. 3d 749, 752 (6th Cir. 2014). Trutek must demonstrate the “validity and reliability of [its expert’s] theories.” *Berry v. Crown Equip. Corp.*, 108 F.Supp.2d 743, 749 (E.D. Mich. 2000).

Federal Rule of Evidence 702, as explicated in *Daubert*, governs the admissibility of expert testimony. Rule 702 provides:

A witness who is *qualified as an expert by knowledge, skill, experience, training, or education* may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help *the trier of fact* to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on *sufficient facts or data*;
- (c) the testimony is the *product of reliable principles and methods*; and
- (d) the expert has *reliably applied the principles and methods* to the facts of the case.

Fed. R. Evid. 702 (emphasis added).

Rule 702 requires courts to ensure that proffered expert testimony is reliable and relevant. *Daubert*, 509 U.S. at 597. “[T]he trial court must determine whether the expert’s training and qualifications relate to the subject matter of his proposed testimony.” *Berry*, 108 F. Supp.2d at 749. To qualify as an expert under Rule 702, “a witness must first establish his [or her] expertise by reference to his [or her] ‘knowledge, skill, experience, training, or education.’” *Eiben v. Gorilla Ladder Co.*, No. 11-CV-10298, 2013 WL 1721677, at *11 (E.D. Mich. April 22, 2013). If the proposed expert “has crossed the foundational threshold of establishing his personal background qualifications as an expert, he must then provide further foundational testimony as to the validity and reliability of his theories.” *Berry*, 108 F. Supp. 2d at 749. A methodology cannot be consider reliable unless, at a

minimum, it is based on objective criteria and subject to independent validation. *Smelser v. Norfolk S. Ry.*, 105 F.3d 299, 303 (6th Cir. 1997).

IV. ARGUMENT

As a matter of law, Trutek facially cannot meet its burden to establish that Ermakov and Burns's methodologies are sufficiently reliable under *Daubert*. In *Mike's Train House, Inc. v. Lionel, L.L.C.*, 472 F.3d 398, 407 (6th Cir. 2006), the Sixth Circuit held that a district court improperly allowed an expert to testify where "there [was] no evidence that his methodology had ever been tested, subjected to peer review, possessed a known or potential rate of error, or enjoyed general acceptance." Courts are "suspicious of methodologies created for the purposes of litigation, 'because expert witnesses are not necessarily always unbiased. . . .'" *Id.* "Establishing that an expert's proffered testimony grows out of pre-litigation research or that the expert's research has been subjected to peer review are the two principal ways the proponent of expert testimony can show that the evidence satisfies the [reliability] prong of Rule 702." *Daubert v. Merrell Dow Pharms.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (affirming grant of summary judgment and exclusion of expert testimony). Thus, a methodology cannot be considered reliable unless, at a minimum, it is based on objective criteria and subject to independent validation. *Smelser*, 105 F.3d at 303. Ermakov's and Burns' Reports and methodologies facially do not satisfy these requirements.

In addition, Ermakov’s and Burns’s test results and conclusions are not sufficiently probative of the ultimate issue for which they are being offered—whether NanoBio satisfies the elements of the asserted claims. Even if the test methodologies were sufficiently reliable (which they are not), the results themselves are irrelevant to the underlying question of infringement. Whether or not NanoBio exhibits a surface electrostatic charge of a similar magnitude to Trutek’s products—on substrates that are not representative of actual *in vivo* conditions of use required by the claims—says nothing about the ultimate question of whether NanoBio exhibits a surface electrostatic charge that attracts and inhibits harmful particulate matter from infecting an individual. In addition to the numerous flaws detailed herein, there can be no dispute that the testing was not designed to determine whether NanoBio actually meets any element of the asserted claims.

A. Ermakov’s and Burns’ Never-Used-Before Methodologies Lack Independent Validation

Courts will not permit experts to invent methodologies for a case. *See Mike’s Train House*, 472 F.3d at 407; *see, e.g., In re SFPP Right-Of-Way Claims*, No. CV-15-07492, 2017 WL 2378363, at *7 (C.D. Cal. May 23, 2017) (finding the expert “invented this methodology for this case” and the “method has never been used to value property before and likely never will be used again” and thus “is not sufficiently reliable under Rule 702”). Here, Ermakov’s and Burns’s methods are unprecedented and designed for the specific purpose of being used in this litigation.

Ermakov admitted he never previously conducted measurements as a consultant, and his experiment in this case was “unique” and “different from, like, anything else [he] ha[d] done before.” (**Ex. 3**, Ermakov Dep. Tr., 15:6–9, 68:5–8.) His research has never focused on: (1) techniques or instrumentation for measuring electrostatic surface charge of pharmaceutical formulations, (2) measuring electrostatic surface charge of water-in-oil nanoemulsions, (3) techniques or instrumentation for measuring electrostatic surface charge for pharmaceutical products that are intended to be applied to the human skin, or (4) techniques or instrumentation to measure the electrostatic surface charge of pharmaceutical products that function through electrostatic forces. (*Id.* at 68:5–69:3.) To the contrary, his only experience in testing surface charge is this case. (*Id.* at 71:2–5.)

Similarly, Burns has never used pigskin as a substrate before. (**Ex. 5**, Burns Dep. Tr., 43:23–44:4, 44:20–24.) Burns has never tested electrostatic charge using the methodology he applied in this case. (*Id.* at 99:3–13, 110:6–10.) Burns has no experience in testing oil-in-water nanoemulsions. (*Id.* at 102:7–9.) In fact, Burns has only performed two other electrostatic charge-related tests on liquids before, and those tests were materially different in-kind. (*See id.* at 99:3–6, 110:6–24.)

Even more concerning, rather than using their own experience and scientifically tested methods, Ermakov and Burns followed the directions of Trutek’s counsel in selecting a substrate—Ermakov using printer paper and Burns

using pigskin. (**Ex. 3**, Ermakov Dep. Tr., 19:5–23; **Ex. 5**, Burns Dep. Tr., 30:22–31:2.) Ermakov does not know if paper is commonly used as a substrate for this type of testing because he does not “have much knowledge of other instances where someone needed to test the charge of some substance” and does not “have that information.” (**Ex. 3**, Ermakov Dep. Tr., 99:8–14.) Burns admitted there is no published paper on the testing of pigskin. (**Ex. 5**, Burns Dep. Tr., 113:25–114:10). Burns also admitted there is no industry standard for testing the electrostatic charge of liquids generally. (*Id.* at 93:4–17.) The method he employed was unique and different from anything he has ever seen. (*See id.* at 99:3–6; 110:6–24.)

Despite their novelty, Ermakov and Burns did not develop their tests based on scientific literature or seek independent validation as required under *Daubert*. *See Smelser*, 105 F.3d at 303; *see also Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 276 (5th Cir. 1998); *United States v. Orr*, 692 F.3d 1079, 1093–94 (10th Cir. 2012). Ermakov did not consult any of his colleagues, or anyone else for that matter, to discuss the validity of his new testing process and apparatus. (**Ex. 3**, Ermakov Dep. Tr., 30:2–6, 46:6–16, 74:6–8.) Ermakov’s test method and apparatus have never been peer reviewed. (*Id.* at 75:21–23.) Ermakov has never seen any publications related to his test method or apparatus. (*Id.* at 75:17–20.) Ermakov similarly did not review any academic literature when creating his never-used-before testing procedure. (*Id.* at 13–20.) Burns is not aware of any published paper on testing with

pigskin, let alone in this field. (**Ex. 5**, Burns Dep. Tr., 113:25–114:6.) Courts do not permit this kind of novel experimentation, invented for the purposes of litigation, to be admitted into evidence. *See Mike’s Train House*, 472 F.3d at 407.

B. The Methods Lack Proper Controls, Calibrations, and Scientific Rigor

The purpose of the reliability inquiry is to ensure that the expert “employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Courts are “obliged to screen expert testimony to ensure it stems from, not just a reliable methodology, *but also a sufficient factual basis and reliable application of the methodology to the facts.*” *KW Plastics v. U.S. Can Co.*, 131 F.Supp.2d 1289, 1292 (M.D. Ala. 2001) (citation omitted). Here, there are several fundamental flaws with Ermakov’s and Burns’s methodologies.

First, Ermakov and Burns make assumption after assumption that various test conditions are not relevant. For example, Ermakov and Burns simply assume that paper and dried pigskin are suitable substitutes for human nasal mucosa. However, in his vast experience, Dr. Amiji explains that paper and pigskin are not indicative of how NanoBio functions when administered to humans *in vivo*, given that human skin and pigskin have different barrier properties, blood vessel structure, and variability. (*See Ex. 1*, Dr. Amiji Responsive Report, ¶¶ 39, 42.) Moreover, the application of chemicals to paper and dry pigskin is not predictive of how

pharmaceutical formulations operate in nasal passages, which are moist. (*Id.* ¶ 42.) Further, the tests were conducted at room temperature, which is not indicative of how a product would function at a typical human body temperature. (*Id.* ¶ 42.)

Ermakov’s and Burns’s methods lack any semblance of scientific rigor and instead rely on pure speculation. For example, Ermakov “didn’t bother with really accurate measurements of how much sample was applied.” (**Ex. 3**, Ermakov Dep. Tr., 85:3–10.) Eyeballing it, he waited until the samples “looked dry.” (*Id.* at 104:6–20.) The apparatus was never calibrated as Ermakov would have needed a sample of a chemical with a known charge, which he never bothered to obtain. (*See id.* at 95:22–96:1.) He did not run any additional samples because he assumed the results would be the same. (*Id.* at 107:20–23.)

Likewise, Burns had no way to determine if pigskin was sufficiently similar to human skin as he would have had “to perform that test,” which he did not. (**Ex. 5**, Burns Dep. Tr., 111:5–10.) While Burns only ran tests on a handful of pigskin substrates (coated in unidentified samples), he did not record the results based on each pigskin individually. (*Id.* at 148:8–16.) Courts simply will not admit testimony based on these kind of loose, fast, and speculative practices. *Anderson v. Bristol Myers Squibb*, No. Civ.A. H-95-0093, 1998 WL 35178199, at *12 (S.D. Tex. Apr. 20, 1998) (“an opinion that is an insightful, or even inspired, hunch is not admissible if it lacks scientific rigor”); *Rosen v. Ciba-Geigy Corp.*, 78 F.3d

316, 319 (7th Cir. 1996) (“The courtroom is not the place for scientific guess work, even of the inspired sort. Law lags science; it does not lead it.”).

Second, neither test includes calibration standards or other procedures for validation. This likely explains why the Ermakov and Burns tests show significant discrepancies and are, indeed, *inconsistent* with one another. (See **Ex. 1**, Dr. Amiji Responsive Report, ¶¶ 39, 44–46.) The discrepancies are large. Burns tested NasalGuard on two occasions—but obtained inconsistent measurements greater than an order of magnitude. Burns’ July 30, 2019 Report, comparing NasalGuard to Zicam® Cold Remedy formulations, determined that Trutek’s NasalGuard had a total average surface electrostatic charge of 16.97 and nanocoulomb charge per square centimeter of .146. (**Ex. 6**, Burns July 30, 2019 Report, p. 5.) However, for the test conducted for this case, Burns found that NasalGuard had a total average surface charge of .25 and a nanocoulomb charge per square centimeter of .003. (**Ex. 4**, Burns Report, p. 5; *see also* **Ex. 5**, Burns Dep. Tr., 67:11–15.)

The tests even diverged as to which product had a higher charge, with Burns and Ermakov reporting opposite results (Burns reporting BlueWillow’s product had a higher charge, as compared to Ermakov reporting Trutek’s product had a higher charge). (See **Ex. 5**, Burns Dep. Tr., 163:15–164:10; **Ex. 1**, Dr. Amiji Responsive Report, ¶ 47.) Indeed, Ermakov testified that the inconsistencies could be the result of error due to application of different volumes of samples. (See **Ex.**

3, Ermakov Dep. Tr. at 115:4–116:6, 119:19–119:20.) Such inconsistent results are a classic “indicia of unreliability.” *Lippe v. Bairnco Corp.*, 99 Fed.Appx. 274, 279 (2d Cir. 2004); *see also In re LIBOR-Based Fin. Instruments Antitrust Lit.*, 299 F.Supp.3d 40, 468, 477–78 (S.D.N.Y. 2018) (this principle “is no less applicable to multiple methodologies intended to measure the same phenomenon that ultimately produce inexplicably inconsistent results.”)

C. Ermakov and Burns Failed to Independently Verify Their Samples

Courts have consistently excluded “fundamentally flawed or unsupported” expert opinions. *See Ellipsis, Inc. v. The Color Works, Inc.*, 428 F.Supp.2d 752, 760 (W.D. Tenn. 2006) (excluding expert opinion based on unverified data from a website); *Coffey v. Dowley Mfg., Inc.*, 187 F.Supp.2d 958, 976 (M.D. Tenn. 2002) (excluding expert opinion based on “guesstimations and speculations”), *aff’d*, 89 Fed. Appx. 927 (6th Cir. 2003). Ermakov and Burns failed to verify the contents and integrity of their test samples, choosing instead to rely on representations from Trutek (who is clearly not independent or disinterested).

Both Ermakov and Burns relied on unidentified samples in generic bottles (provided by Trutek) without verifying their contents, how they were prepared, their expiration dates, or determining whether or not they were contaminated during preparation. (**Ex. 3**, Ermakov Dep. Tr., 42:19–43:2, 79:9–12; **Ex. 5**, Burns Dep. Tr., 48:7–11, 53:12–54:8.) Burns also used pigskin samples as a substrate

without verifying their integrity. Burns does not know where the pigskin was obtained, when it was obtained, or how it was stored. (**Ex. 5**, Burns Dep. Tr., 130:14–22, 131:10–17.) It is inappropriate to admit Ermakov’s and Burns’s testimony as they cannot provide even a basic foundation for their opinions—i.e., the test results they purport to provide are attributable to an unexpired sample of NanoBio or whether NanoBio was in fact the material tested.

Courts have consistently excluded this kind of uncritical acceptance of information provided by counsel. *See Campbell v. AMTRAK*, 311 F.Supp.3d 281, 301 (D.D.C. 2018) (“Dr. Finkelman appears to have uncritically relied on documents supplied to him by plaintiffs’ counsel, cited to those pieces of evidence that supported his theories, and concluded that this selective evidence” supports his theory.); *Mathison v. Boston Sci. Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *25 (S.D.W. Va. May 6, 2015) (excluding expert opinions finding “I [] have no way to ensure that plaintiffs’ counsel did not provide Dr. Trepeta with only those pathology reports that tended to strengthen, rather than refute, Dr. Trepeta’s opinions.”); *cf. Lipitor (Atorvastatin Calcium) MKtg. v. Pfizer, Inc.*, 892 F.3d 624, 634 (4th Cir. 2018) (“courts have consistently excluded testimony that ‘cherry-picks’ relevant data.”).

D. Ermakov's and Burns's Results are Not Probative

Even assuming Ermakov's and Burns's novel methodologies are deemed reliable (which they should not), their testimony is still not probative of any material fact related to infringement. Other than asserting that Trutek's product and BlueWillow's product have charges within the same magnitude, Ermakov and Burns failed to test or ascertain whether those charges are capable of electrostatically attracting and inhibiting particulate matter, as required by the '802 patent claims. Likewise, Ermakov's test does not even indicate whether the charge is positive or negative, an element that is required by the '802 patent claims in order to "electrostatically attract" negatively charged particles. In other words, the Burns and Ermakov testing bears no relation to whether NanoBio practices any element of the asserted '802 patent claims. Nor has there been any showing, based on reliable proof and evidence, that NasalGuard practices the claimed invention.

As such, the comparison of the two products and conclusion they exhibit a surface charge "of the same order of magnitude" has no relevance to the infringement issues in this litigation. More pointedly, even had that showing been made, "[i]nfringement is not determined by comparison between commercial products sold by the parties." *Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1481 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 924 (1984). There is "no room for consideration of the patentee's products." *Eastman Kodak Co. v. Agfa-Gevaert*

N.V., 540 F.Supp.2d 227, 296 (W.D.N.Y. 2008) (citing *AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320, 1328 (Fed. Cir. 2007)). Thus, a comparison of the products is materially unhelpful to the trier of fact and must be excluded. *See, e.g., Sysmex Corp. v. Beckman Coulter, Inc.*, No. 19-1642, 2022 WL 2292059, at *2 (D. Del. June 24, 2022) (“BCI shall not compare the accused products to Sysmex’s commercial products and the prior art”).

V. CONCLUSION

For the reasons stated herein, BlueWillow requests that the Court exclude the Reports and testimony of Ermakov and Burns in their entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on March 15, 2023, I filed the foregoing document and this Certificate of Service with the Court using the ECF system.

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